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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,365	01/18/2002	Mayumi Kotani	SAEGU92.001APC	7977

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
VANIK, DAVID L	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,365	KOTANI ET AL.	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 10-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, and 10-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Request for Continued Examination filed on 3/21/2005.

Receipt is also acknowledged of Applicant's Amended Claims filed on 10/26/2004.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 10-24 drawn to a composition comprising kaempferol-3-glucoside and a method of treating **pollinosis** by administering kaempferol-3-glucoside to a subject who suffers from pollinosis.

Group II, claim(s) 25-30 drawn to a method of treating **pollinosis** by administering kaempferol-3-glucoside to a subject who previously suffered from pollinosis in a specific season.

Group III, claim(s) 31-36, drawn to a method of treating **atopic dermatitis** by administering kaempferol-3-glucoside to a patient who suffers from atopic dermatitis.

Group IV, claim(s) 37-42, drawn to a method of treating **atopic dermatitis** by administering kaempferol-3-glucoside to a patient before showing symptoms of atopic dermatitis.

2. The inventions listed as Groups I – IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I and II claim a method of treating pollinosis by administering kaempferol-3-glucoside to a patient whereas Groups III and IV are drawn to a method of treating atopic dermatitis. Pollinosis and atopic dermatitis are recognized as different disorders. The special technical feature of Groups I and II is a method of treating pollinosis by administering kaempferol-3-glucoside to a patient. On the other hand, the special technical feature of Groups III and IV is a method of treating atopic dermatitis by administering kaempferol-3-glucoside to a patient. Since pollinosis and atopic dermatitis encompass different patient populations, the special technical feature of Groups I and II and Groups III and IV are different.

Because the method of Group I is distinct from Group II, these Groups can also be distinguished on the basis of a special technical feature. Specifically, Group I is drawn to a method of treating pollinosis by administering kaempferol-3-glucoside to a subject who **suffers** from pollinosis whereas Group II is drawn to a method of treating pollinosis

by administering kaempferol-3-glucoside to a subject who **previously suffered from pollinosis in a specific season**. On this basis, Groups I and II comprise distinct special technical features because they are each drawn to a different patient population. Methods of treating a patient who previously suffered from a disorder can be substantially different from methods of treating a patient currently suffering from a disorder.

Because the method of Group III is distinct from Group IV, these Groups can also be distinguished on the basis of a special technical feature. Specifically, Group III is drawn to a method of treating atopic dermatitis by administering kaempferol-3-glucoside to a patient who **suffers** from atopic dermatitis whereas Group IV is drawn to a method of treating atopic dermatitis by administering kaempferol-3-glucoside to a patient **before showing symptoms** of atopic dermatitis. On this basis, Groups I and II comprise distinct special technical features because they are each drawn to a different patient population. Methods of treating a patient that has yet to show symptoms of a disorder can be substantially different from methods of treating a patient currently suffering from a disorder.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

4. The following is a list of administration forms as set forth in claims 12, 27, 33 and 39:

1) orally,

2) intravenously,

3) topically,

4) intramuscularly,

5) intracutaneously,

6) subcutaneously,

7) intraperitoneally,

8) aerosolization

If applicant selects Group I, II, III or IV, one species from the administration forms group must be chosen to be fully responsive.

The claims are deemed to correspond to the species listed above in the following manner: oral, intravenously, topically, intramuscularly, intracutaneously, subcutaneously, intraperitoneally, and aerosolization are species a generic category, modes of administration.

The following claim(s) are generic: Claim 24, 25, 31 and 37.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: oral, intravenously, topically, intramuscularly, intracutaneously, subcutaneously, intraperitoneally, and aerosolization are functionally distinct modes of administration.

5. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Due to the complexity of the action, examiner submitted the Election Restriction in writing in lieu of calling applicant's attorney.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588 . The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615

4/18/05

CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500